IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION

CARMEN R. HARDY,	*	
Plaintiff,	*	
vs.	*	CASE NO. 4:09-CV-119 (CDL)
PHARMACIA CORPORATION, *et al.*,	*	
Defendants.	*	

O R D E R

Plaintiff moves to compel responses to her requests for production (ECF No. 26). For the following reasons, the motion to compel is granted in part and denied in part. Defendants are ordered to produce the requested Dilantin, Cerebyx, phenytoin, and fosphenytoin labels and product guides for the years 2002-present.[1]

BACKGROUND

Plaintiff claims that she was injured because she ingested Defendants' anti-seizure medication product, Dilantin, in 2007. Among other things, Plaintiff alleges that she developed severe skin conditions, including Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis, because she ingested Dilantin. Plaintiff also claims that Dilantin caused her permanent eye damage.

[1] Plaintiff is not presently seeking to compel responses to its document requests that seek product labels and guides for *any* of Defendants' products that specifically reference black patients or other sub-groups.

Plaintiff asserts that Defendants failed to provide adequate warnings regarding the risks of Dilantin. Among other things, Plaintiff contends that Defendants did not adequately warn of increased risks of several hypersensitivity reactions in black patients. According to Plaintiff, the Dilantin product label used in the United States was updated in 2009 to warn of these increased risks, but previous versions of the label—including the one that existed in 2007 when Plaintiff ingested Dilantin—did not.

DISCUSSION

Plaintiff asks the Court to compel responses to Requests 1-13 of her First Requests for Production of Documents. Plaintiff seeks "labels for any and all Dilantin, Cerebyx, phenytoin, or fosphenytoin products sold or marketed by" Defendants "in all countries in the world for the years 1995-Present."[2] Pl.'s Mot. to Compel Ex. 1, Pl.'s 1st Req. for Prod. of Docs 9, 15-16, ECF No. 26-2. Plaintiff also seeks existing English translations of labels for these products. *Id.* at 10; Pl.'s Reply in Supp. of Mot. to Compel 9, 15-16 ("If the English translation exists,

[2] With regard to Defendant Pfizer, Plaintiff seeks these documents from "Defendant Pfizer or any of Pfizer's affiliates, subsidiaries, sister organizations, related entities, agents, or divisions." *E.g.*, Pl.'s Mot. to Compel Ex. 1, Pl.'s 1st Req. for Prod. of Docs 9, ECF No. 26-2. Requests 3-4 seek labels and English translations "for any and all Dilantin, Cerebyx, phenytoin or fosphenytoin products sold or marketed by Pfizer or any of Pfizer's affiliates, subsidiaries, sister organizations, related entities, agents, or divisions" in certain countries and regions listed on Pfizer's website. Pl.'s Mot. to Compel Ex. 1, Pl.'s 1st Req. for Prod. of Docs 10-12, ECF No. 26-2.

Plaintiff is entitled to it and it should be produced. If no English translation of a particular foreign label already exists, then Plaintiff agrees that Defendants should not be required to create one."). Plaintiff further seeks "patient medication guides, patient information guides, consumer information guides, or other documents for distribution to patients" for these products. Pl.'s Mot. to Compel Ex. 1, Pl.'s 1st Req. for Prod. of Docs 12-14, ECF No. 26-2. Plaintiff also seeks existing English translations of these documents. *Id.* at 14-15. Finally, Plaintiff seeks the labels (and their English translations) "which specifically reference African Americans, black patients, or any other sub-group or sub-population." *Id.* at 16.

Defendants object to producing the labels and product guides. Defendants contend that (1) Plaintiff seeks labels and guides related to products that are not at issue in this case, (2) the labels and other documents Plaintiff seeks are irrelevant and outside the scope of discovery, (3) Plaintiff is not entitled to labels and guides referencing sub-groups and product risks other than those that are specifically at issue in this case, and (4) Plaintiff's requests are cumulative because Plaintiff's counsel already obtained several foreign labels in another case. Defendants also contend that if the Court orders Defendants to produce the labels and product guides, the Court

should order Plaintiff to bear the cost of the production. Defendants appear to concede that the documents Plaintiff seeks are in Defendants' possession, custody, or control.

I. Standard for Discovery

"Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense[.]" Fed. R. Evid. 26(b)(1). "Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." *Id.*

II. Products Other than Dilantin/Phenytoin

Plaintiff seeks discovery of product labels and guides for Dilantin, Cerebyx, phenytoin, and fosphenytoin. Defendants summarily argue that the request is overbroad because "[o]ther medications' labeling content are [sic] not important to resolving whether the Dilantin® label was adequate." In support of this argument, Defendants rely on *Bouchard v. American Home Products Corp.*, 213 F. Supp. 2d 802, 811 (N.D. Ohio 2002), in which the district court granted a motion in limine to exclude from trial evidence of a drug that was "chemically similar" but "not the same" as the drug at issue in that case.

Bouchard does not support Defendants' argument that Plaintiff may not discover information about other drugs that are very similar to or the same as Dilantin. The product

Dilantin contains the active ingredient phenytoin. The product Cerebyx contains the active ingredient fosphenytoin. According to Plaintiff, fosphenytoin is "the same drug with a different delivery route." Pl.'s Mem. in Supp. of Mot. to Compel 11, ECF No. 26-1. Defendants have not disputed this statement, and the Court concludes that Plaintiff's request for the fosphenytoin and Cerebyx labels is not overbroad.

III. Relevance of Labels and Guides Sought by Plaintiff

Defendants contend that the labels and medication guides sought by Plaintiff are irrelevant and outside the scope of discovery. Defendant contends that the documents sought are "foreign regulatory materials" that are only relevant on issues of foreign regulatory actions and foreign law. The Court disagrees.

To establish her failure to warn claim, Plaintiff must show that (1) Defendants had a duty to warn, (2) Defendants breached that duty, and (3) the breach was the proximate cause of Plaintiff's injuries. *E.g., Dietz v. SmithKline Beecham Corp.*, 598 F.3d 812, 815 (11th Cir. 2010) (applying Georgia law). Under Georgia's learned intermediary doctrine, a prescription drug manufacturer "does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer." *Id.* (internal

quotation marks omitted). The warnings to the doctor "must be adequate or reasonable under the circumstances of the case." *McCombs v. Synthes (U.S.A.)*, 277 Ga. 252, 253, 587 S.E.2d 594, 595 (2003).

Defendants contend that the foreign labels are not relevant in this action because at least one of them references case reports, which are ordinarily not sufficient to prove causation in prescription drug cases. Defendants further assert that the foreign labels are not relevant because they merely show that foreign regulatory bodies acted more quickly than the U.S. Food and Drug Administration "to add" a stronger warning regarding certain risks of Dilantin.[3] Defendants also argue that the product guides are not relevant because Georgia's learned intermediary doctrine did not require Defendants to warn end users of their products regarding the products' potential risks.

Defendants miss the point. The present question for the Court is whether the request for the foreign labels and guides is reasonably calculated to lead to the discovery of admissible evidence—not whether the labels and product guides will be admissible at trial.[4] Even if the foreign labels and product

[3] The Court notes that Defendants, not the FDA, are responsible for the content of their product labels. *Wyeth v. Levine*, 555 U.S. 555, ____, 129 S. Ct. 1187, 1198 (2009).

[4] Defendant asserts that "courts have repeatedly held that evidence of foreign regulatory actions and labeling are irrelevant in American litigation, even where plaintiffs contend those decisions are relevant to 'notice' in failure-to-warn cases." Defs.' Resp. to Pl.'s Mot. to

guides are not ultimately admissible at trial in this case, they could lead Plaintiff to discover admissible evidence regarding whether Defendants' warnings to Plaintiff's physician were adequate and reasonable under the circumstances. *Cf. Wyeth v. Levine*, 555 U.S. 555, ____, 129 S. Ct. 1187, 1197 (2009) (noting that, after the first incident of severe complications similar to those experienced by the plaintiff, similar complications continued to occur, and the pharmaceutical company could have analyzed data regarding the similar complications and added a stronger warning regarding the drug). For example, Plaintiff could use the labels and product guides to discover what Defendants knew about the potential risks of the products at issue here, when Defendants knew about those potential risks, what follow-up investigations Defendants did to learn more about those potential risks, and other facts that are potentially relevant to the risk-utility analysis. For these reasons, the Court finds that the labels and guides Plaintiff seeks are not outside the scope of permissible discovery.

IV. Labels Referencing Black Patients and other Sub-Groups

Plaintiff seeks all phenytoin and fosphenytoin foreign labels that reference black patients and other sub-groups,

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Compel 9, ECF No. 27. Two Florida district court cases excluding evidence of foreign regulatory actions regarding prescription drugs *from use at trial* do not persuade the Court that the request for foreign labels in this case is not reasonably calculated to lead to the discovery of admissible evidence.

whether or not the labels warn of the increased risks of hypersensitivity reactions at issue here. Defendants contend that this request is overbroad and that discovery should be limited to information regarding whether Plaintiff's doctor was adequately warned about the risks specific to one sub-group (black patients) and the risks that actually affected Plaintiff. The learned intermediary doctrine is not so restricted, and the Court declines to narrow Plaintiff's request to one sub-group or specific risks.

V. "Cumulative" Labels Sought by Plaintiff

According to Defendants, Plaintiff has located three pre-2007 foreign phenytoin labels for a product manufactured by Pfizer subsidiaries, and those labels warn that there could be increased risks of several hypersensitivity reactions in black patients. Defendants argue that discovery of any other foreign labels is cumulative and duplicative of the documents Plaintiff has already obtained by other means. Defendants also argue that it would be less burdensome for Plaintiff to find foreign labels "[t]hrough other means and litigation." Defs.' Resp. to Pl.'s Mot. to Compel. 17, ECF No. 27. Defendants offer no explanation as to why it would be less burdensome for Plaintiff to find the foreign labels, which are in Defendants' possession, custody, or control.

As discussed above, Plaintiff's request for the labels and guides is reasonably calculated to lead to the discovery of admissible evidence. The fact that Plaintiff's counsel has obtained a couple of labels by other means does not establish that discovery of additional labels would be so cumulative or duplicative that the discovery should not be permitted.

VI. Time Frame

Plaintiff seeks labels and patient guides for the years 1995-present. Defendants contend that the time frame of the request is overbroad, and the Court agrees. Plaintiff's claim focuses on the United States Dilantin label as it existed in 2007. Plaintiff contends that Defendants began warning in foreign labels of increased risks of several hypersensitivity reactions in black patients "at least as early as 2004." Pl.'s Mot. to Compel 8, ECF No. 26-1. Plaintiff offers no explanation why she needs labels that existed sixteen years ago—twelve years before Plaintiff ingested Dilantin. Without such an explanation, the Court declines to compel production of labels and patient guides for such an expansive timeframe and concludes that Defendants should only be required to produce labels and patient guides for the years 2002-present.

VII. Cost Shifting

Defendants argue that the cost of any production of the labels and guides should be shifted to Plaintiff. Defendants

contend that their burden of producing the labels and guides Plaintiff seeks would be significant and would outweigh the "complete lack of benefit" to Plaintiff because the documents lack "any relevance" to the case. Defs.' Resp. to Pl.'s Mot. to Compel 15-16, ECF No. 27. As discussed above, the labels and guides are potentially relevant and are not cumulative, so there is no "complete lack of benefit" to Plaintiff.

According to Defendants' "conservative estimate," it would take "over two hundred weeks of dedicated employee time" and cost "hundreds of thousands of dollars" to produce the labels. *Id.* at 16. Defendants do not explain why the production process would be so lengthy and expensive. The estimate assumes that Defendants would have to produce labels and guides going back to 1995 and that Defendants would need to create translated versions of the documents that have not already been translated. As discussed above, discovery of the labels and guides is limited to 2002-present. Also, Plaintiff agrees that Defendants are not required to create new documents—such as translations—in response to Plaintiff's document requests, so Defendants will not be required to translate any documents.

The scope of the production required by the Court is narrower than the scope of the production contemplated by Defendants in projecting the cost of the production. And, again, the labels and guides are potentially relevant and not

cumulative, so there is no "complete lack of benefit" to Plaintiff. Therefore, the Court finds that cost-shifting is not warranted in this case.

CONCLUSION

For the reasons set forth above, Plaintiff's Motion to Compel (ECF No. 26) is granted in part and denied in part. The attorneys for the parties shall confer within fourteen days of today's order to develop a reasonable time frame for production of the documents.

IT IS SO ORDERED, this 27th day of May, 2011.

S/Clay D. Land
CLAY D. LAND
UNITED STATES DISTRICT JUDGE